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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,204	10/24/2001	Grigori N. Enikolopov	1314.1044-017	3409

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EXAMINER

CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/23/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,204

Applicant(s)

ENIKOLOPOV ET AL.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-37, 41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 20-37, 41 and 42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 20-22, drawn to a method of increasing a population of dividing cells in a tissue of a mammal comprising contacting the cells with at least one inhibitor of nitric oxide;
- II. Claims 23-25, drawn to a method of decreasing a population of cells in S phase in tissue of a mammal and inducing differentiation of the cells, comprising contacting the tissue with at least one enhancer of nitric oxide;
- III. Claims 26-27, drawn to a method of coordinating developmental decisions of a cell type in a mammal comprising introducing nitric oxide into the cell type or precursor of the cell type, thereby inhibiting proliferation of the cell type or precursor of the cell type and inducing differentiation of the cell type or precursor of the cell type;
- IV. Claims 28-32, drawn to a method of regenerating tissue in an adult mammal comprising a selected tissue with at least one inhibitor of nitric oxide, thereby inhibiting differentiation and inducing proliferation of cells of the tissue, then contacting the selected tissue with a compound which inhibits proliferation and induces differentiation;
- V. Claims 33-37, drawn to a method of repopulating an organ or tissue having normally nondividing cells comprising contacting a selected organ

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or tissue with an least one inhibitor of nitric oxide, thereby inhibiting differentiation and inducing proliferation of cells of the organ or tissue, then contacting the selected organ or tissue with a compound which inhibits proliferation and induces differentiation; and.

- VI. Claims 41 and 42 drawn to a method of increasing a population of cells in S phase in a tissue of a mammal, comprising contacting the tissue with an inhibitor of nitric oxide.

Applicants' claims are separate and distinct since they require active agents having different characteristics. The nitric oxide inhibitors are different from nitric oxide enhancers. They have each acquired a separate classification in the pharmaceutical art. For example a nitric oxide inhibitor is L-NAME classified in class 514 461+ and a nitric oxide enhancer is sodium nitroprusside classified in class 514, subclass 609+. The physiological aspect of the claims also exemplifies the claims are separate and distinct since they require the proliferation, decrease and coordination of cells. Each activity is physiologically separate and distinct since they relate to the growth of a cell, e.g. cancer and the inhibition of the growth of a cell, e.g., a treatment for encephalitis.

.Because these inventions are distinct for the reasons given above and the search required for each Group is different and requires different considerations s to the physiological effect, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.


Theodore J. Criares
Primary Examiner
Art Unit 1617

tjc
April 21, 2003